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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,580	02/28/2002	Gene A. Bornzin	A02P1021	9022

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,580	BORNZIN ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8,11-18,21-28,31-38,41-44,46-48,51-58 and 61 is/are rejected.

7)☒ Claim(s) 9,10,19,20,29,30,39,40,45,49,50,59 and 60 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 February 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/28/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 7, 8, 11-13, 15, 21, 22, 24, 27, 31-33, 35, 41, 42, 44, 47, 51-53, 55 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreyenhagen et al. (Pat. No. 5,282,836).

Regarding claims 1 and 21, Kreyenhagen et al. clearly disclose the recited atrial fibrillation detecting means 70, the ventricular pacing pulse generating means 78 for applying a pacing pulse to at least one of the ventricles responsive to the detection of atrial fibrillation (note col. 3, lines 49-56), and the defibrillation pulse generating means 76 for applying defibrillating electrical energy to the atria after a timing means 64 times a time period. While timer 64 is not recited as timing a time period beginning with an evoked response and ending with the subsequent T-wave, the claim language does not require such operation. A timer that is capable of timing the period between ventricular activations (R-waves or evoked responses as set forth in Fig. 2 with the loop comprising elements 119b and 120-124) is considered to be a timer that times a period "...through an evoked response and T-wave caused by the ventricular pacing pulse." Timer T_B can time a time period beginning with a pacing pulse (causing an evoked potential), and continue timing through a companion T-wave until the timer expires initiating another pacing pulse. The claim does not require that the timer stop timing on a T-wave, but may continue through such an event and end sometime thereafter. A timer that times the R-R interval, for example, would also read on this limitation.

Regarding claim 7 and related claims, Kreyenhagen et al. disclose that a pacing pulse is generated when the timer times a cardiac interval of T_B that is longer than a minimum cardiac interval. The applicant has not defined the term "minimum cardiac

interval" in the claim and thus any minimum interval can be arbitrarily assigned such as a detected fibrillation interval.

Regarding claim 11 and related claims, note elements 123 and 119b of Fig. 2. It should be noted that one could consider a "last one" of the pacing pulses to be simply the most recent pacing pulse of a series of pacing pulses.

Claim 12 is clearly anticipated (note for example col. 8, lines 40-44).

Regarding claim 31, note again the comments made in the rejection of claims 1 and 21 above in reference to the interpretation of the phrase "...through the evoked response and T-wave."

Similar comments to those made above in the rejection of claims 1 and 21 apply to claim 41. Because claim 41 is broader in scope than claim 21, further interpretations of the Kreyenhagen et al. reference are possible. For instance, one can say that the method of Kreyenhagen et al. only applies defibrillating electrical energy to the atrium in step 125 (Fig. 2) after a T-wave of a previous cycle has ended (such as for example a T-wave occurring prior to decision diamond 122 registering a true condition).

Related comments to those set forth in the rejection of claim 41 apply to claim 61 as well.

The applicants should note that any claims not specifically addressed above but containing substantially similar limitations to those claims addressed above, have been treated in the same manner.

3. Claims 1-4, 7, 11-15, 21-24, 27, 31-35, 41-44, 47, 51-55 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra (Pat. No. 6,081,745).

Regarding claim 1, Mehra discloses an implantable cardiac stimulation device comprising an atrial fibrillation detector (note col. 6, lines 38-68), a pacing pulse generator 216 that applies a pacing pulse to at least one of the ventricles responsive to the atrial fibrillation detector detecting atrial fibrillation, a timer that times a time period through an evoked response and a T-wave caused by the pacing pulse (note the timer that times the synchronization interval 411), and a defibrillation pulse generator (elements 234, 236, etc.) that applies the defibrillating electrical energy to at least one atrium of the heart responsive to the timer completing the timing of the time period (note

col. 9, lines 15-22). As shown in Fig. 3, the synchronization interval extends from a ventricular pacing pulse 408 through the evoked response 410 and continues for typically 400 milliseconds (see col. 9, lines 10-13). Given that the time period specified in the prior art is in the midst of the time period advocated by the applicants in claim 3, the examiner considers it inherent that the device of Mehra times through a T-wave caused by the pacing pulse. Even if the prior art timer were by accident to time through the T-wave periodically, the art would still read on the claim. In the case of a T-wave ending prior to the expiration of the 400 millisecond time period, the defibrillation pulse is applied after expiration and the sensing of the next R-wave. Generating energy responsive to the timer completing its time period does not require that the shock be issued immediately thereafter. Related comments apply to independent claims 21, 41 and 61.

Regarding claim 7 and claims with similar limitations, the examiner considers the determination of the ventricular escape interval from measuring the R-R intervals subsequent to atrial fibrillation to represent a cardiac interval longer than a minimum cardiac interval. The applicant has not defined the term "minimum cardiac interval" in the claim and thus any minimum interval can be arbitrarily assigned such as a detected fibrillation interval.

Regarding claim 11 and claims with similar limitations, note col. 12, lines 37-52.

Regarding claim 12 and claims with similar limitations, note col. 5, lines 43-56.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 5, 6, 16, 17, 25, 26, 36, 37, 46, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreyenhagen et al. (Pat. No. 5,282,836).

Regarding claim 5 and claims with similar limitations, although Kreyenhagen et al. apply the pacing pulse to the right ventricle, the left ventricle is also a well-known pacing site from which to elicit ventricular contraction. Since the whole point of applying the pacing pulse is to stabilize the heart rate, those of ordinary skill in the art would have seen the pacing of the left ventricle to be an obvious equivalent to right ventricular pacing. Any pacing location capable of propagating an action potential through the heart would have been considered suitable to the practice of the Kreyenhagen et al. invention, with the ultimate electrode location depending on the particular condition of the patient under treatment and individual heart specifics.

Similar comments apply to claim 6 and related claims wherein the examiner takes Official Notice that bi-ventricular pacers are old and well-known by artisans of ordinary skill in the art.

6. Claims 8, 18, 28, 38, 48 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreyenhagen et al. or Mehra in view of Rahul (Pat. No. 5,411,524).

While neither Kreyenhagen et al. or Mehra discuss the detection of an evoked potential and inhibiting application of defibrillating energy in the absence of such a detection, Rahul discloses a related device that determines capture (i.e., the evoked potential) prior to initiating a defibrillation shock (note col. 4, lines 55-68). The determination of capture is an important safety precaution in order to avoid basing an action on an event that may not have occurred due to loss of capture. In order to ensure proper operation and avoid acting on misinformation, those of ordinary skill in the art would have seen the obviousness of incorporating the evoked response detector of Rahul into the systems of either Kreyenhagen et al. or Mehra.

Allowable Subject Matter

7. Claims 9, 10, 19, 20, 29, 30, 39, 40, 45, 49, 50, 59, 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

There does not appear to be a teaching in the prior art of record for modifying the Kreyenhagen et al. or Mehra references to incorporate the recited atrial pacing pulse generator that applies pacing after the timer completes the timing of the time period and before the defibrillation pulse generator applies a defibrillating shock. Nor does there appear to be a teaching for modifying the above references for sensing P-waves and applying energy to the atria in timed relation to a sensed P-wave.

Regarding claim 45, the prior art of record does not disclose the detection of the T-wave in an apparatus of the type set forth.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 7, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER